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Reld W. Von Borstel

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EXAMINER

LEWIS, PATRICK T

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte REID W. VON BORSTEL

Appeal 2009-015179
Application 09/763,955
Technology Center 1600

Before ERIC GRIMES, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This is an appeal under 35 U.S.C. § 134 involving claims to a method for treating diseases associated with mitochondrial dysfunction. The Examiner has rejected the claims for nonenablement and, provisionally,

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

for obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the nonenablement rejection and affirm the provisional double patenting rejection.

STATEMENT OF THE CASE

Claims 48-50, 55, 62-64, and 68 are on appeal. Claim 48 is representative and reads as follows:

48. A method for treating a congenital mitochondrial disease selected from the group consisting of Mitochondrial Encephalomyopathy, Lactic Acidemia, Lerber's Hereditary Optic Neuropathy; Mitochondrial neurogastrointestinal encephalomyopathy; Progressive External Ophthalmoplegia; Leigh's Disease; in a mammal comprising administering to said mammal in need of such treatment an effective amount of a pyrimidine nucleotide precursor selected from the group consisting of uridine, an acyl derivative of uridine, cytidine and an acyl derivative of cytidine.

I.

The Examiner has provisionally rejected claim 55 for obviousness-type double patenting based on claims 31, 32, and 38-41 of application 09/930,494 (Answer 7). Appellant does not dispute the merits of the rejection but state that he "will consider filing a Terminal Disclaimer when otherwise allowable subject matter is indicated" (Appeal Br. 13). Because Appellant has not disputed the merits of the Examiner's provisional rejection, we affirm it.

II.

Issue

The Examiner has rejected claims 48-50, 55, 62-64, and 68 under 35 U.S.C. § 112, first paragraph, on the basis that the Specification does not

enable a skilled worker to practice the claimed method without undue experimentation (Answer 3). The Examiner finds that the treatment of mitochondrial disorders was ineffective and unpredictable at the time of the invention and cites Przyrembel² as supporting evidence (*id.* at 4-5), as well as the Specification's statement that metabolic cofactors and vitamins have not been generally useful as therapeutics (*id.* at 6). The Examiner acknowledges the Specification's working examples but finds that they are limited to triacetyluridine (*id.* at 7) and concludes that they "are not sufficient to support applicant's claim of the treatment of the instantly claimed disorders" (*id.*).

Appellant contends that Przyrembel does not support the rejection because it was "published in 1987, approximately eight years before the priority date of the present application" (Appeal Br. 11) and is not indicative of the state of the art at the relevant time (*id.* at 12). Appellant also contends that "Examples 1, 3, 7, 8 and 9 of the present application all deal with respiratory chain defects and further support enablement of the invention as claimed" (*id.*).

The issue with respect to this rejection is: Has the Examiner provided evidence or sound scientific or logical reasoning sufficient to support a conclusion that practicing the claimed method would require undue experimentation?

² Przyrembel, *Therapy of Mitochondrial Disorders*, 10 J. INHER. METAB. Dis. 129-146 (1987).

Findings of Fact

1. The Specification states that “[t]reatment of diseases involving mitochondrial dysfunction has heretofore involved administration of vitamins and cofactors. . . . However, while useful in isolated cases, no such metabolic cofactors or vitamins have been shown to have general utility in clinical practice in treating mitochondrial diseases.” (Spec. 2.)
2. The Specification states that “administration of pyrimidine nucleotide precursors is effective in treatment of a large variety of symptoms and disease states related to mitochondrial dysfunction” (*id.* at 8).
3. The Specification states that “compounds and compositions of the invention are useful for treatment of a very broad spectrum of signs and symptoms in mitochondrial diseases with different underlying molecular pathologies” (*id.* at 22).
4. The Specification states that “functional or conditional pyrimidine deficiency underlies a wide variety of dominant symptoms in patients with mitochondrial diseases and . . . pyrimidine supplementation is sufficient to improve or ameliorate a broad variety of symptoms in such patients” (*id.* at 23).
5. The Specification provides a working example that describes treatment of a patient with multisystem mitochondrial disorder with triacetyluridine (*id.* at 40). The Specification states that the treatment “caused improvements in virtually all features of a complex multisystem disease related to mitochondrial dysfunction in a variety of tissues” (*id.* at 41).

6. The Specification provides a working example that describes treatment of a patient with Leigh's Syndrome who displayed renal tubular acidosis (*id.* at 42). The Specification states that "[w]ithin several hours after beginning intragastric treatment with triacetyluridine . . . , her renal tubular acidosis resolved" and other symptoms improved (*id.*).

7. The Specification provides a working example describing treatment of a mouse model for Huntington's disease with triacetyluridine (TAU) (*id.* at 46). The Specification states that "[t]here was decreased mortality . . . in the mice treated with TAU compared to the controls" (*id.*) as well as decreased motor impairment (*id.* at 47).

8. Przyrembel discloses that

[m]itochondrial disorders . . . are heterogenous in clinical picture and in response to therapeutic attempts. Defects of fatty acid metabolism are amenable to therapy by dietary means . . . and in some cases with vitamins. Defects in pyruvate metabolism do not respond to therapy except in some special cases. Therapeutic attempts include dietary measures, vitamins as coenzyme precursors. Defects in the respiratory chain appear to respond to treatment only in exceptional cases.

(Przyrembel 129, abstract.)

Principles of Law

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

“Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct.” *In re Armbruster*, 512 F.2d 676, 678 (CCPA 1975).

Analysis

The Specification states that the claimed method is useful in treating “a very broad spectrum of signs and symptoms in mitochondrial diseases” (FF 3) and to “ameliorate a broad variety of symptoms” in patients with mitochondrial disease (FF 4). As a basis for doubting these assertions, the Examiner cites Przyrembel (Answer 5).

However, as Appellant points out, Przyrembel was published in 1987 and therefore has little weight as evidence of the state of the art in 1998, the apparent effective filing date of the instant application. In addition, the Examiner has not pointed to any discussion in Przyrembel of the claimed method of treating mitochondrial disease using pyrimidine supplementation. The fact that other treatments may have proved ineffective is scant evidence that the *claimed* method would not be effective. The same is true of the Specification’s statement that metabolic cofactors and vitamins have not been generally useful for treating mitochondrial disease (FF 1).

The Examiner also points out that all of the working examples in the Specification use a single compound (triacyluridine) (Answer 7). The Examiner does not, however, provide any evidence that the results obtained with triacyluridine are not indicative of the results that would be obtained using other acyl derivatives of uridine or cytidine, or with uridine or cytidine themselves, as recited in the claims. The Examiner therefore has not shown

that the working examples are not representative of the full scope of the claimed method.

In short, the Examiner has not carried the burden of providing an adequate basis for concluding that the full scope of the claims on appeal are not adequately enabled by the instant Specification. *See In re Wright*, 999 F.2d at 1561-62.

SUMMARY

We affirm the provisional rejection of claim 55 for obviousness-type double patenting, but reverse the rejection of claims 48-50, 55, 62-64, and 68 for nonenablement.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

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